

Appl. No. 10/798,677
Amdt. dated January 18, 2008
Reply to O.A. of October 18, 2007

Remarks

I. Status

In this amendment, claims 80, 102, 109, 110, and 126 have been canceled, which leaves claims 1-79, 81-101, 103-108, 111-125, and 127-136 pending and at issue.

Support for the amendments to claims 1, 23, 33, 43, 54, 74, 95, 98, 103, 105, 106, 111, 112, 113, 116, 118, and 127-131 can be found in the specification at least as follows: a positional device that determines a position of a point on an anatomical structure or is adapted to determine a relative position of a finger mounted structure in relation to the positional device at least in paragraphs 17, 24, and 25; a flexible glove at least in paragraph 19; reaching through an incision at least in paragraph 27; a structure movable in relation to a sensor at least in paragraphs 26 and 27; and a magnetic tracker and a magnetic sensor at least in paragraph 30.

The undersigned thanks Examiner Chao for the courtesies extended during a telephonic interview conducted on November 26, 2007, between Examiner Chao and the undersigned during which the rejection of the claims over the references was discussed. The following remarks summarize and amplify the substance of the interview.

II. Traversals of Rejections and Arguments for Patentability

Applicants traverse the rejection of the claims at issue under 35 U.S.C. §103(a) as obvious over Shechtman et al. U.S. Patent No. 6,524,260 ("Shechtman") in view of Bova et al. U.S. Patent No. 6,390,982 ("Bova"), or further in view of any of various combinations of Pearlman U.S. Patent No. 7,141,019 ("Pearlman"), Ustuner U.S. Patent No. 6,746,402, Sliwa, Jr. et al. U.S. Patent No. 6,511,427, Danisch U.S. Patent No. 5,321,257, Walbrink et al. U.S. Patent No. 5,449,356, Magasi U.S. Patent No. 4,826,492, and Touzawa et al. U.S. Publication No.2003/0198372.

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The applied references do not disclose or suggest a system for determining a global position of an anatomical structure of a patient's body, as recited by claims 1-22, that includes a substrate adapted to be removably mounted to an outer surface of a user's body, a sensor attached to the substrate, a positional device attached to the substrate, and a structure adapted to be mounted to a finger of the user, wherein the structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the structure in relation to the positional device.

Further, the applied references do not disclose or suggest a method for determining a position of a point on an anatomical structure of a patient using a surgical navigation system, as recited by claims 23-53, comprising the steps of mounting a substrate in a removable manner to an outer surface of a user's body, the substrate having a positional device and a sensor that can be detected by the surgical navigation system, covering a fingertip of the user with a finger mounted structure, wherein the finger mounted structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the finger mounted structure with respect to the positional device, placing the finger mounted structure on the point of the anatomical structure to be determined, calculating the relative position of the finger mounted structure in relation to the positional device, and determining the position of the point from the relative position of the finger mounted structure.

Further still, the applied references do not disclose or suggest a system for determining a global position of an object, as recited by claims 54-73, wherein the system includes a substrate comprising a glove, a sensor attached to the substrate that can be tracked by a navigation system, a positional device attached to the substrate that can determine a position of a point on an object, and a structure mounted to a finger of the glove, wherein the structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the structure in relation to the positional device, and further comprising a first circuit for calculating a global position of a point on the object by correlating a position of the sensor and the relative position of the structure.

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Yet further, the applied references do not disclose or suggest a method for determining a position of a point on an object using a navigation system, as recited by claims 74-79 and 81-94, that includes the steps of mounting a glove on a user's hand, wherein the glove has a positional device that determines a position of a point on an object and a sensor that can be detected by a surgical navigation system, disposing a finger mounted structure on a finger of the glove, wherein the finger mounted structure is movable in relation to the sensor, placing the finger mounted structure on the point of the object to be determined, and determining the position of the point.

Furthermore, the applied references do not disclose or suggest an apparatus for determining a position of a point on an anatomical structure, as recited by claims 95-101 and 103-108, that includes a glove adapted to be mounted on a hand of a user, a sensor and a magnetic tracker attached to the glove, a structure comprising a magnetic sensor mounted to a finger of the glove, wherein the magnetic sensor is movable in relation to the sensor, and wherein the magnetic tracker determines a relative position of the magnetic sensor, and further comprising a first circuit for calculating the position of the point on the anatomical structure by correlating a position of the sensor and the relative position of the magnetic sensor.

Additionally, the applied references do not disclose or suggest a method for determining a position of a point on an anatomical structure through a small incision opening, wherein the point is obstructed from the incision, as recited by claims 111-125 and 127-136, that includes the steps of mounting a substrate in a removable manner to an outer surface of a user's body, covering a tip of the user's finger with a finger mounted pointer that has a rigid tip, wherein the finger mounted pointer is capable of communicating with an external positional device mounted on the substrate in moving proximity to the incision opening and the external positional device is associated with a sensor mounted on the substrate, manipulating the finger mounted pointer so that the rigid tip is in contact with the point to be determined, determining the relative position of the finger mounted pointer in relation to the sensor, determining the global position of the sensor, and determining the global position of the point from the relative position of the finger mounted pointer and the global position of the sensor.

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A. Modification of Shechtman with the teachings of Bova, as proposed in the pending Office action, would render Shechtman unsatisfactory for its intended purpose and substantially change the principle of operation of Shechtman.

Shechtman does not disclose a system or method wherein both a sensor and a positional device or magnetic tracker are located on a single substrate adapted for mounting on a user in order to obtain a position of a point on the patient. In fact, Shechtman teaches away from such a modification because it would cause Shechtman to be unsuitable for its intended purpose or else require such substantial modification of Shechtman as to substantially change the principle of operation of Shechtman.

If a proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See M.P.E.P. § 2143.01 (V) (citing *In re Gordon*, 773 F.2d 900, (Fed. Cir. 1984)).

Further, if the modification or combination proposed by an examiner would change the principle of operation of the prior art reference being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. See M.P.E.P. § 2143.01 (VI) (citing *In re Ratti*, 270 F.2d 810 (CCPA 1959)).

Shechtman discloses in FIG. 4 a reference sensor 32 that is attached to the patient in a fixed, known position with respect to the spine and a movable probe 30 that is associated with the user's finger. The probe 30 is not attached to the same substrate as the sensor 32 because Shechtman requires the use of the sensor 32 as a fixed reference point with respect to the spine. Therefore, in order to operate in the manner intended by Shechtman, the reference sensor 32 cannot be attached to the user or the movable probe 30 because such an attachment would cause the sensor 32 to no longer be in a fixed, known position with respect to the spine. As such, Shechtman would not be able to make the necessary calculations considered therein for mapping the spine using the known reference location of the sensor 32 according to the principles of differential mapping envisioned by Shechtman.

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Specifically, Shechtman states that "FIG. 4 illustrates a probe, therein generally designated 30, used with a reference sensor, generally designated 32, attached to [a patient's] body at a fixed and known location with respect to a predetermined reference point of the spine 34." Shechtman 6:43-47. The reference sensor 32 is used in combination with the separate probe 30 so that "the position tracking system will track the movements of the probe 30 with respect to the reference 32; and since the position of the reference 32 is known with respect to the spine 34, the tracked movements of the probe trace the curvature of the spine." Shechtman 6:47-51. Further, the "[r]eference sensor 32 . . . may be the magnetic field generator itself which also thereby serves as a reference with respect to probe 30. Shechtman 6:59-63.

From the above statements, it is clear that the item 32 must provide a fixed reference point with respect to the spine of the patient, and that the probe 30, which is used to determine positions of points on the spine to trace the curvature thereof with reference to the fixed position of item 32, must be separate from the item 32 in order to work by the principles envisioned by Shechtman.

Other embodiments disclosed in Shechtman as at FIGS. 2 and 3 do not overcome the deficiencies pointed out with respect to the two embodiments disclosed with reference to FIG. 4 because such other embodiments require the finger of the user to be in a fixed position with relation to the position sensor 4 (FIG. 2) or position sensor 22 (FIG. 3), as pointed out in detail in applicant's previous response, Amendment A.

Therefore, Shechtman teaches away from any modification of the reference sensor 32 to include the probe 30, because to do so would eliminate either the necessary reference point or the ability to trace the curvature of the spine, which would render Shechtman unsatisfactory for its intended purpose of providing a precise contour mapping system. *See* MPEP § 2143.01(V).

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In addition, the suggested modification of Shechtman with Bova to add a sensor to the substrate that can be tracked by a surgical navigation system does not overcome the above noted deficiencies of Shechtman because such a modification of Shechtman with the teachings of Bova would require a substantial reconstruction and redesign of the overall system of Shechtman. Specifically, Shechtman is designed to provide contour mapping of the patient's spine based on calculations that require the sensor 32 to be in a fixed, known position with respect to the patient's spine. To modify Shechtman with Bova to allow the sensor 32 of Bova to not be in the fixed, known position, requires a completely different set of position vector calculations that are not contemplated by the system in Shechtman. Therefore, there would have been no reason to make the modifications to Shechtman using Bova, as proposed in the Office, action because such modification would change the underlying principal of operation of Shechtman.

The remaining applied references do not overcome the deficiencies pointed out above respecting the proposed combination of Shechtman and Bova with respect to all of the claims at issue.

For at least these reasons, the proposed combination of Shechtman and Bova fails to support a *prima facie* case of obviousness of any of the claims at issue, and the rejections of the all claims at issue as obvious thereover should be withdrawn, notice of which is respectfully requested.

B. Pearlman does not overcome the deficiencies pointed out with the proposed modification of Shechtman with the teachings of Bova.

Applicants also traverse the combination of Shechtman, Bova, and Pearlman, as suggested in the pending Office action, as teaching a glove that has both a sensor and a positional device, as recited by claims 6, 30, 33, 54-79, 81-101, and 103-108. As discussed above, Shechtman teaches away from a substrate that includes both a sensor and a positional device, regardless of whether the substrate is a glove.

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Further, applicants specifically traverse the argument proffered in the Office action that "it would have been obvious . . . to use a substrate which is a glove. . . . [because] [s]uch a modification can be considered applying a known technique to a known device ready for improvement to yield predictable results." Office action at pages 5-6. However, as pointed out above, the reference sensor 32 in Shechtman is designed to provide a fixed reference point with respect to the patient's spine by being placed on the back of the patient in a known position in relation to the patient's spine. Placing the reference sensor 32 and probe 30 on the same glove would not provide a satisfactory fixed reference point with respect to the patient's spine. Therefore, the Shechtman was not "ready for improvement" nor would the use of a glove instead of the reference sensor 32 attached to the patients body have yielded "predictable results," as erroneously suggested in the Office action.

Referring more specifically to the method claims 23-53, 74-79, 81-94, 111-125, and 127-136, the substrate or glove is mounted to a user's body. In contrast, the reference sensor 32 of Shechtman is mounted to a patient's body, not a user's body. Further, it would not have been obvious to modify Shechtman to place the reference sensor 32 on the user's body rather than on the patient's body because Shechtman specifically teaches away from this modification by requiring the "fixed and known" positional relationship between the reference sensor and the patient's spine. Shechtman 6:45-47. If the reference sensor were to be placed on the user's body, then the sensor would not serve its intended purpose of providing a reference point with respect to the patient. For this further reason, Shechtman does not disclose or suggest the substrate or the glove of claims 23-53, 74-79, 81-94, 111-125, and 127-136.

For these additional reasons, claims 6, 23-79, 81-101, 103-108, 111-125, and 127-136, are not obvious over the applied references, and the pending rejections thereover should be withdrawn, notice of which is respectfully requested.

C. Shechtman teaches away from a structure adapted to cover an end of a finger of a user or covering a finger tip of the user.

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Applicants further traverse the suggestion in the pending Office action that Shechtman may disclose or suggest covering a fingertip of the user with a finger mounted structure, as recited by claims 23-53, a structure mounted to a finger of a glove, as recited by claims 54-73, 95-101, and 103-108, disposing a finger mounted structure on a finger of a glove, as recited in claims 74-79 and 81-94, or covering a tip of the user's finger with a finger mounted pointer having a rigid tip, as recited in claims 111-125, and 127-136.

Rather, Shechtman discloses a probe 30 in FIG. 4, which is only shown as a non-descript black rectangle located on the first distal joint of the user's finger. No additional relevant description regarding the probe 30 is disclosed. However, Shechtman also discloses a rigid probe 2 that is "constructed such that when it is grasped by a user's hand, the outer tip of the index finger of the user's hand is at a predetermined position with respect to a position sensor carried by the probe." Shechtman 4:58-61. Shechtman requires that the tip of the user's fingers extend past the rigid probe 2 so that the "fingers are thus utilized as the 'feeling part' of the probe." Shechtman 2:34-41. Therefore, Shechtman actually teaches away from the suggestion in the pending Office action that it would have been obvious to extend the probe to cover an end of the user's finger, because to do so would render Shechtman unsatisfactory for its intended purpose of allowing the user to feel the outer surface of a patient's spine to provide a precise contour mapping system. *See* MPEP § 2143.01(V).

IV. Conclusion

For at least these reasons, applicants respectfully request reconsideration and allowance of the foregoing claims.

If there are any issues remaining that can be resolved by telephone, the examiner is invited to call the undersigned.

Deposit Account Authorization

The Commissioner is hereby authorized to charge any deficiency in any amount enclosed or any additional fees which may be required during the pendency of this application under 37 CFR 1.16 or 1.17, except issue fees, to Deposit Account No. 50-1903.

Respectfully submitted,


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